UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,968	09/26/2005	Wei Sun	46528-5047-00-US (415078)	6096

10872 7590 01/21/2011

Riverside Law LLP
300 Four Falls Corporate Center, Suite 710
300 Conshohocken State Road
West Conshohocken, PA 19428

EXAMINER	
JONES, HUGH M	

ART UNIT	PAPER NUMBER
2128	

NOTIFICATION DATE	DELIVERY MODE
01/21/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

dockets@riversidelaw.com
dcoccia@riversidelaw.com
dpratcher@riversidelaw.com

Office Action Summary	Application No.	Applicant(s)	
	10/540,968	SUN ET AL.	
	Examiner	Art Unit	
	Hugh Jones	2128	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 November 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/10/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-10 are pending.

Response to Amendment

2. The declaration filed on 11/10/2010 under 37 CFR 1.131 has been considered but is ineffective to overcome the applied prior art reference.

3. The evidence submitted is insufficient to establish a conception of the invention prior to the effective date of the Boland reference. While conception is the mental part of the inventive act, it must be capable of proof, such as by demonstrative evidence or by a complete disclosure to another. Conception is more than a vague idea of how to solve a problem. The requisite means themselves and their interaction must also be comprehended. See *Mergenthaler v. Scudder*, 1897 C.D. 724, 81 O.G. 1417 (D.C. Cir. 1897). In this case, Applicants have presented two different exhibits, one directed to modeling and layered manufacturing fabrication of heterogeneous objects including Boolean algorithms, and the other directed to pictures or drawings of multi-nozzle printers. There is no nexus between the two teachings; either from the two exhibits themselves, or from declarant's statement. Such a nexus is required by the claimed invention. The exhibits, as presented and as explained are unrelated to each other. Furthermore, the inventions recited in claims 3-9 are simply not disclosed by any combination of the two exhibits.

4. The evidence submitted is insufficient to establish a reduction to practice of the invention in this country or a NAFTA or WTO member country prior to the effective date of the Boland reference, for the same reasons.

5. The declaration is also deficient because it is not signed by all inventors.

6. It is unclear why Applicants refer to an unpublished manuscript, wherein said manuscript corresponds, at least in relevant part, to the inventor's 2000 paper, submitted with the simultaneously filed information disclosure statement of 11/10/2010. Statements regarding the unpublished manuscript are therefore taken as admission with respect to the submitted 2000 paper. In other words, the paper discloses all aspects of the claimed invention except for a teaching of multi-nozzle ink jet printers, as per the declaration.

Information Disclosure Statement

7. Applicants are kindly requested to provide the following papers by the inventor:

Darling, A., Sun, W. and Subbaraman, G., "**BioModeling Assisted Three-Dimensional Organ Printing**", Biomedical Engineering: Recent Developments: Editor, J. Vossoughi, 2002 Medical and Engineering Publishers, Inc., **Sept.**, **2002**, pp. 237-238.

Lau, W., Bradbury, T., Youssef, A., Gaylo, C., Sun, W. and Lau, A., "XML Representation and Process Algorithm for Layered Manufacturing of Heterogeneous Objects", Proceedings of 13rd Solid Freeform Fabrication Symposium, Austin, TX, August 5-8, 2002, pp. 255-266.

D'Costa, D., Dimovski, S., Lin, F., El-Raghy, A., Barsoum, M. and Sun, W., "Three-Dimensional Printing of Layered Machinable Ductile Carbide," Proceedings of Eleventh Solid Freeform Fabrication Symposium, University of Texas, Austin, TX, August 7-9, 2000.

Hu, X., Jiang, T., Lin., F. and Sun, W., "Reasoning Boolean Operation for Modeling, Simulation and Freeform Fabrication of Heterogeneous Objects," Proceedings of Eleventh Solid Freeform Fabrication Symposium, University of Texas Austin, August 7-9, 2000.

Jiang, T., Lin, F., Kaltman, S. and Sun, W., "Anatomical Modeling and Rapid Prototyping Assisted Surgical Reconstruction," Proceedings of the Eleventh Solid Freeform Fabrication Symposium, University of Texas Austin, August 7-9, 2000.

Lin, F., Sun, W. and Yan, Y., "A Mathematical Description of Layered Manufacturing Fabrication," Proceedings of the 10th Solid Freeform Fabrication Symposium, Austin, TX, August 9-11, 1999, pp. 139 - 146.

Sun, W. and Lau, A., "A Knowledge-enriched CAD Modeling and Solid Free-form Realization for Heterogeneous Material Structures," Proceedings of the Seventh International Conference on Rapid Prototyping, San Francisco, CA, March 31 - April 3, 1997, pp. 79 - 87.

Applicants are reminded of their duty to disclose information material to patentability under the provisions of 37 CFR 1.56. The Examiner considers the listed references very material and relevant.

Claim Interpretation

8. The following interpretations are noted: Claims 5, 7-8 are process claims, not product-by-process claims; they are directed to intended use and therefore are provided no patentable weight; Claim 10: "for *simultaneously depositing specified hydrogels with*

different viscosities" refers to intended use – no patentable weight. The claims are directed to a multi-nozzle biopolymer deposition apparatus. "*thereby constructing a scaffold from the designed scaffold model*" also refers to intended use and is therefore provided no patentable weight.).

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 1-10 are rejected under 35 U.S.C. 102(e) as clearly anticipated by Boland et al. (US 7,051,654).

11. Boland discloses:

1. A process for manufacturing complex parts and devices comprising:

(a) utilizing a CAD environment to design a part or device to be created *and*
(b) converting the CAD designed part or device into a heterogeneous material and multi-part assembly model which can be used for multi-nozzle printing; and

Col. 14:

Using the techniques described above, it has been discovered that cells may be printed onto a substrate and remain viable. However, not only does the present invention provide a mechanism for ensuring cell survival, it also provides the ability to easily, quickly, and inexpensively manipulate the types of patterns, densities, etc., that may be printed. For instance, the printed patterns may be simple or complex, and have a shape that is regular or irregular. In fact, due to the control provided by the present invention, there is essentially no limit on the patterns or shapes capable of being printed according to the present invention.

Col. 15:

Regardless of the pattern and/or density selected, the present invention may utilize various control techniques to ensure that the desired results are achieved. Unlike conventional techniques for printing cells that involve contact-deposition, the present invention provides a precise, well-controlled method of printing that does not substantially risk contamination. The non-contact, ink-jet printing techniques employed in the present invention also allow for better control than previously realized when depositing viable cells onto a substrate. Generally speaking, any well-known ink-jet printing control technique may be utilized in the present invention. For instance, a printer driver may be used to control the movement of the printer head, the movement of the substrate, the voltage delivery to the printer head, etc. Some suitable ink-jet printing control techniques that may be adapted for use in the present invention are described in

Referring to FIG. **8**, for instance, a block diagram of one embodiment of a control system that may be used in the present invention is shown. As shown, the system includes a host computer **500** and an ink-jet printer **100** (FIG. 1). In the host computer **500**, the exchange of various data and control are generally performed between an OS (Operating System) **501** and application software **502** that operates on the OS **501**. Print data is exchanged between the OS **501**, the application software **502**, and a printer driver **503**, and is sent to the printer **110** through the printer driver **503**. The present invention is by no means limited to any particular printer driver because, as is well known to those skilled in the art, numerous types of printer drivers may accomplish the same functions desired in the present invention.

The flow of data in the process of printing out cell composition(s) from the printer **100** is generally described below. Typically, a user first inputs the desired cell density and pattern into the application software **502**. These data signals are then sent to the printer driver **503**. The printer driver **503** performs processing for the received signals, and also generally converts them into binary signals. The printer driver **503** sends these signals to the interface, in the host computer **500**, which is used for the printer **100** or the interface for a file storage unit or the like. The signals are then sent as output to the interface for the printer **100**, and the data signals are sent to controller software **601** in the printer **100**. Matching between the set print mode and a printer head **110** is checked. Thereafter, the print data is transferred to engine software **602**. In this case, the engine software **602** interprets the received data as data indicating the print mode and the data structure designated by the controller software **601**, converts the print data into discharge pulses, and sends them to the printer head **110**. With this operation, cell composition(s) are discharged from the printer head **110**. The ID information of the printer head **110**, the ID information of each cell composition reservoir, etc., are sent to the engine software **602**. On the basis of these

(c) printing the designed part or device using multiple, different, specialized nozzles.

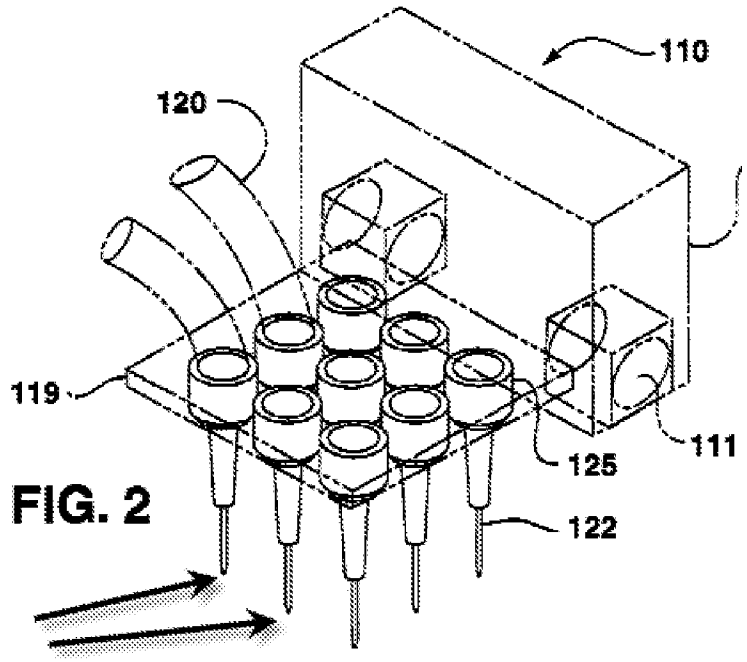

FIG. 2

Col. 4:

Generally speaking, any known ink-jet printer and/or ink-jet printing system may be incorporated for use in the present invention. Ink-jet printers are typically either "DOD" (Drop-On-Demand) or "continuous" ink-jet printers. In a continuous ink-jet printer, a stream of fluid con-

In addition, various ink-jet printers used to print layers on plastic parts (known as "rapid prototyping") may also be adapted for use in the present invention. One example of such a printer is the ModelMaker II™ printer available from Solidscape, Inc. (formerly "Sanders-Prototype, Inc."). The

Col. 6:

In the illustrated embodiment, the deposition portion **133** includes a housing **137** into which a fluid flows. To facilitate deposition accuracy, the housing **137** may have a conical shape so the diameter of the housing **137** is about 4 millimeters at the top portion and about 2 millimeters at the bottom portion. From the housing **137**, the fluid then flows to a hollow needle or tube **139**. The size of the needle **139** depends on the type of fluid, the substrate, the printing pattern, and other factors. However, it is generally desired that the needle **139** is large enough to allow any particulates to pass therethrough without substantial sticking or clogging, but small enough to provide the desired deposition accuracy. For example, in one embodiment the needle **139** is a 30-gauge needle that allows cells up to about 100 micrometers in diameter to pass therethrough without substantial sticking or clogging. Of course, smaller and larger needles **139** are also contemplated in the present invention. For instance, in some embodiments, cells having diameters of up to several hundred micrometers (e.g., cell aggregates) may be printed in accordance with the present invention.

Col. 15:

Regardless of the pattern and/or density selected, the present invention may utilize various control techniques to ensure that the desired results are achieved. Unlike conventional techniques for printing cells that involve contact-deposition, the present invention provides a precise, well-controlled method of printing that does not substantially risk contamination. The non-contact, ink-jet printing techniques employed in the present invention also allow for better control than previously realized when depositing viable cells onto a substrate. Generally speaking, any well-known ink-jet printing control technique may be utilized in the present invention. For instance, a printer driver may be used to control the movement of the printer head, the movement of the substrate, the voltage delivery to the printer head, etc. Some suitable ink-jet printing control techniques that may be adapted for use in the present invention are described in

Referring to FIG. **8**, for instance, a block diagram of one embodiment of a control system that may be used in the present invention is shown. As shown, the system includes a host computer **500** and an ink-jet printer **100** (FIG. 1). In the host computer **500**, the exchange of various data and control are generally performed between an OS (Operating System) **501** and application software **502** that operates on the OS **501**. Print data is exchanged between the OS **501**, the application software **502**, and a printer driver **503**, and is sent to the printer **110** through the printer driver **503**. The present invention is by no means limited to any particular printer driver because, as is well known to those skilled in the art, numerous types of printer drivers may accomplish the same functions desired in the present invention.

The flow of data in the process of printing out cell composition(s) from the printer **100** is generally described below. Typically, a user first inputs the desired cell density and pattern into the application software **502**. These data signals are then sent to the printer driver **503**. The printer driver **503** performs processing for the received signals, and also generally converts them into binary signals. The printer driver **503** sends these signals to the interface, in the host computer **500**, which is used for the printer **100** or the interface for a file storage unit or the like. The signals are then sent as output to the interface for the printer **100**, and the data signals are sent to controller software **601** in the printer **100**. Matching between the set print mode and a printer head **110** is checked. Thereafter, the print data is transferred to engine software **602**. In this case, the engine software **602** interprets the received data as data indicating the print mode and the data structure designated by the controller software **601**, converts the print data into discharge pulses, and sends them to the printer head **110**. With this operation, cell composition(s) are discharged from the printer head **110**. The ID information of the printer head **110**, the ID information of each cell composition reservoir, etc., are sent to the engine software **602**. On the basis of these

Col. 17:

A modified Canon® Bubble Jet 2100 printer was used to print the bacteria cells onto the coverslip substrate. The Canon® printer was modified by removing the rubber rolls and removing the center springs, and tightening the remaining springs designed to advance paper.

Microsoft PowerPoint software was used to edit a linear colony array pattern with a 2 drops per millimeter density and 0.13 pt weight (Microsoft® PowerPoint™). A black ink-jet cartridge was emptied of its contents, thoroughly cleaned with a 100% ethanol solution, rinsed using autoclaved water, and dried in a sterilized hood. Thereafter, the cartridge was filled with 1 milliliter of a bacterial printing suspension.

A modified HP® DeskJet 550C printer was used to print the bacteria cells onto the microscope slide substrate. The HP® printer was modified with gear mount pillars having closer tolerances, which was accomplished by adding a horizontal support, changing the transistor in the circuit to one with higher amplification, and re-entering the horizontal position encoder. Both printers utilized a printer driver to allow different viscosities of solutions to be printed. The printer drivers constantly adjusted the voltages to the nozzles to account for different impedances of the solutions, thus allowing the appropriate amount of solution to be dispensed. The printer drivers are available for download at the following website: http://130.127.152.24.

2. The process of claim 1 further comprising using Boolean, scaling, smoothing, mirroring, to modify the CAD design prior to conversion into a heterogeneous material and multi-part assembly model.

Col. 14:

Using the techniques described above, it has been discovered that cells may be printed onto a substrate and remain viable. However, not only does the present invention provide a mechanism for ensuring cell survival, it also provides the ability to easily, quickly, and inexpensively manipulate the types of patterns, densities, etc., that may be printed. For instance, the printed patterns may be simple or complex, and have a shape that is regular or irregular. In fact, due to the control provided by the present invention, there is essentially no limit on the patterns or shapes capable of being printed according to the present invention.

Col. 15:

Referring to FIG. **8**, for instance, a block diagram of one embodiment of a control system that may be used in the present invention is shown. As shown, the system includes a host computer **500** and an ink-jet printer **100** (FIG. 1). In the host computer **500**, the exchange of various data and control are generally performed between an OS (Operating System) **501** and application software **502** that operates on the OS **501**. Print data is exchanged between the OS **501**, the application software **502**, and a printer driver **503**, and is sent to the printer **110** through the printer driver **503**. The present invention is by no means limited to any particular printer driver because, as is well known to those skilled in the art, numerous types of printer drivers may accomplish the same functions desired in the present invention.

3. The process of claim 1 wherein in step (a) data taken from MRI, CT or other patient specific data is imported into the CAD environment to design the part or device to be created. Col. 16:

The techniques for printing viable cells in accordance with the present invention may be employed in a wide variety of applications. One such application is the formation of genomic and protein expression libraries. For instance, these libraries typically require high throughput screening of thousands of bacteria cells to identify specific DNA sequences, investigate gene expression, and/or search for differentially expressed genes. Patterns of bacteria cells may also be printed according to the present invention to build biosensors, such as to monitor environmental components and detect toxicological contamination. In addition, artificial chromosome libraries and other cell-based sensors may also be formed. The present invention may also be employed in tissue engineering and even organ production.

4. The process of claim 1 wherein a biomimetic and non-biomimetic feature is designed into the part or device.

(Note that plainly stated biomimetics refers to human-made processes, substances, devices, or systems that imitate nature (mimetic: Late Latin *mimeticus,* from Greek *mimētikos,* from *mimeisthai* to imitate, from *mimos* mime; from Gk. *Bio-,* comb. form of *bios* "life, course or way of living"). The non-biomimetic scaffold is used to grow the biomemtic (cells/organ) portion.)

In this context, see col. 10:

Besides gels, other support compounds may also be utilized in the present invention. Extracellular matrix analogs, for example, may be combined with support gels to optimize or functionalize the gel. One or more growth

The manner in which the support compound and/or cells may be deposited onto a substrate may generally vary. For instance, FIG. **4** is a schematic illustration of one embodiment in which layers are deposited onto a substrate **216** using the printer **100** of FIG. **1**. Initially, the substrate **216** is supplied at an end **211** of the feed mechanism **114** (FIG. **1**). The wheels **135** of the feed mechanism **114** rotate clockwise, so that the substrate **216** is moved closer to the printer head **110**. After reaching the desired position, the wheels **135** stop so that the printer head **110** is positioned to deposit the fluids at the desired location. In this embodiment, three fluids (the same or different) are supplied from reservoir(s) (not shown) to nozzles **210**, **212**, and **214** of the printer head **110**. The printer head **110** may make multiple passes over the substrate **216**. For instance, in one embodiment, the printer head **110** moves back and forth in the **-x** direction to make multiple passes over the substrate **216** as it rests on the feed

5. The process of claim 1 wherein the part or device comprises a tissue engineering device and printing in step (c) involves direct deposition of cells or biological factors.

(intended use for the process. These are process claims, not product-by-process claims. No patentable weight provided; limitation "d" is not considered in view of the ambiguity and Applicant's silence on this issue. Regardless, Boland teaches both direct and non-direct contact. See title: "Ink-jet printing of viable cells"). Col. 17:

A modified HP® DeskJet 550C printer was used to print the bacteria cells onto the microscope slide substrate. The HP® printer was modified with gear mount pillars having closer tolerances, which was accomplished by adding a horizontal support, changing the transistor in the circuit to one with higher amplification, and re-entering the horizontal position encoder. Both printers utilized a printer driver to allow different viscosities of solutions to be printed. The printer drivers constantly adjusted the voltages to the nozzles to account for different impedances of the solutions, thus allowing the appropriate amount of solution to be dispensed. The printer drivers are available for download at the following website: http://130.127.152.24.

Col. 16:

> The techniques for printing viable cells in accordance with the present invention may be employed in a wide variety of applications. One such application is the formation of genomic and protein expression libraries. For instance, these libraries typically require high throughput screening of thousands of bacteria cells to identify specific DNA sequences, investigate gene expression, and/or search for differentially expressed genes. Patterns of bacteria cells may also be printed according to the present invention to build biosensors, such as to monitor environmental components and detect toxicological contamination. In addition, artificial chromosome libraries and other cell-based sensors may also be formed. The present invention may also be employed in tissue engineering and even organ production.

Col. 17:

> A modified Canon® Bubble Jet 2100 printer was used to print the bacteria cells onto the coverslip substrate. The Canon® printer was modified by removing the rubber rolls and removing the center springs, and tightening the remaining springs designed to advance paper.

Boland also discloses that direct contact was standard in the art, and that non-direct has certain advantages: Col. 15:

> Regardless of the pattern and/or density selected, the present invention may utilize various control techniques to ensure that the desired results are achieved. Unlike conventional techniques for printing cells that involve contact-deposition, the present invention provides a precise, well-controlled method of printing that does not substantially risk contamination. The non-contact, ink-jet printing techniques employed in the present invention also allow for better control than previously realized when depositing viable cells onto a substrate. Generally speaking, any well-known ink-jet printing control technique may be utilized in the present invention. For instance, a printer driver may be used to control the movement of the printer head, the movement of the substrate, the voltage delivery to the printer head, etc. Some suitable ink-jet printing control techniques that may be adapted for use in the present invention are described in

6. The process of claim 5 wherein direct cell deposition improves histological accuracy, cell ratios, and spatial patterning of cells in the part or device.

(The limitation is directed to a subjective test and furthermore refers to an intended purpose. However, the consequence appears to be an inherent result of the cause – the direct deposition)

7. The process of claim 1 wherein the part or device produced comprises an artificial organ, a tissue scaffold, an artificial vasculature or channel system, or a sample for cytotoxicity testing.

(intended use for the process. These are process claims, not product-by-process claims. No patentable weight provided).

8. The process of claim 1 wherein the part or device produced comprises a biochip, biosensor, bionic, cybernetic, mechanoactive, or a bioactive tissue scaffold.

(intended use for the process. These are process claims, not product-by-process claims. No patentable weight provided).

9. The process of claim 1 wherein the part or device is **used** in drug delivery.

(Intended use – no patentable weight provided. The claims are directed to a process for manufacturing complex parts and devices.

10. A multi-nozzle biopolymer deposition apparatus comprising:

(a) a data processing system which processes a designed scaffold model and converts it into a layered process tool path;

(see limitations a, b, of claim 1)

(b) a motion control system driven by the layered process tool path:

(see limitations a, b, of claim 1)

(c) a material delivery system comprising multiple nozzles of different types and sizes for *simultaneously depositing specified hydrogels with different viscosities thereby constructing a scaffold from the designed scaffold model.*

("**for *simultaneously depositing specified hydrogels with different viscosities***" *refers to intended use* – no patentable weight. The claims are directed to a multi-nozzle biopolymer deposition apparatus."***thereby constructing a scaffold from the designed scaffold model***" also refers to intended use and is therefore provided no patentable weight.)

See fig. 2:

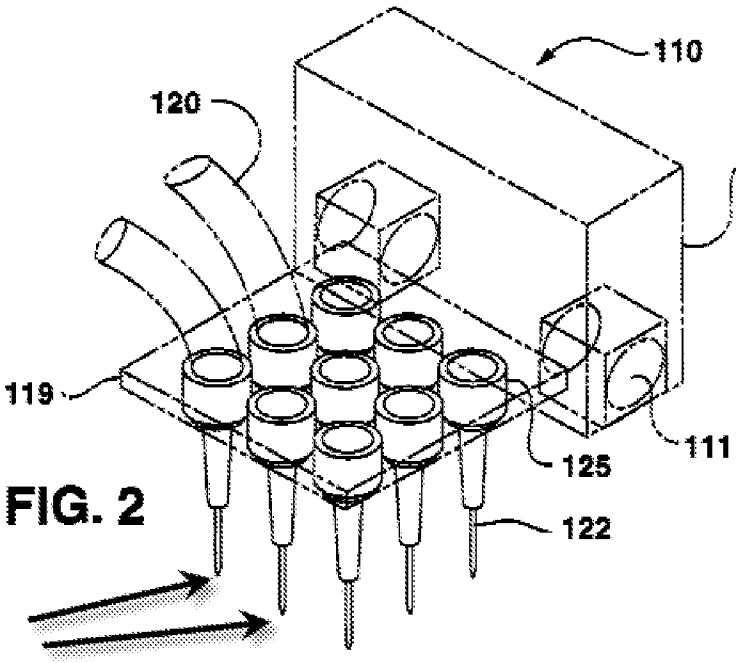

FIG. 2

Regardless, see Col. 17:

position encoder. Both printers utilized a printer driver to allow different viscosities of solutions to be printed. The printer drivers constantly adjusted the voltages to the nozzles to account for different impedances of the solutions, thus allowing the appropriate amount of solution to be dispensed. The printer drivers are available for download at the following website: http://130.127.152.24.

As for scaffolds, see col. 10:

Besides gels, other support compounds may also be utilized in the present invention. Extracellular matrix analogs, for example, may be combined with support gels to optimize or functionalize the gel. One or more growth

The manner in which the support compound and/or cells may be deposited onto a substrate may generally vary. For instance, FIG. **4** is a schematic illustration of one embodiment in which layers are deposited onto a substrate **216** using the printer **100** of FIG. **1**. Initially, the substrate **216** is supplied at an end **211** of the feed mechanism **114** (FIG. **1**). The wheels **135** of the feed mechanism **114** rotate clockwise, so that the substrate **216** is moved closer to the printer head **110**. After reaching the desired position, the wheels **135** stop so that the printer head **110** is positioned to deposit the fluids at the desired location. In this embodiment, three fluids (the same or different) are supplied from reservoir(s) (not shown) to nozzles **210**, **212**, and **214** of the printer head **110**. The printer head **110** may make multiple passes over the substrate **216**. For instance, in one embodiment, the printer head **110** moves back and forth in the **-x** direction to make multiple passes over the substrate **216** as it rests on the feed

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

14. Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hu et al. (IDS, 11/10/2010) in view of Sun et al. (*Computer Methods and Programs in Biomedicine* 67 (2002) 85–103), and Applicant's statements in the affidavit of 11/10/2010.

15. Applicants state in the declaration:

> 7. I invented and reduced to practice the claimed apparatus, as well as the claimed processes the apparatus performs, prior to February 22, 2003, as evidenced by the subject matter described and illustrated in both the unpublished, draft manuscript I created and the depictions of the apparatus I created prior to February 22, 2003.
>
> 8. The unpublished manuscript of Exhibit A describes the process for construction of heterogeneous CAD modeling based composite unit cells. As explained in the unpublished manuscript of Exhibit A, the constructed unit cell is a multi-volume based CAD model with material heterogeneity assigned as a design attribute in the volume. Modified Boolean operation with reasoning merging and extracting is developed to execute the object manipulation between different materials (volumes). The heterogeneous unit cell model is capable of capturing the designed geometrical configuration and reinforcement orientation at the individual constituent phases, as well as retaining the distinctive reinforcement and matrix material properties. In addition, the developed unit cell model is also intended for implementation with available CAD/CAE/CAM systems for integrated design, simulation, and manufacturing of advanced composites.
>
> 9. The unpublished depictions of Exhibit B illustrate various designs of a multi-nozzle biopolymer deposition apparatus for implementing the processes described in the unpublished manuscript of Exhibit A. The depicted apparatus of Exhibit B is a multi-nozzle printer designed to process the desired scaffold model and convert it into a layered process tool path, as well as to simultaneously deposit materials to construct the scaffold.
>
> 10. It is my understanding that the pending claims (claims 1-10) of the present application read on the subject matter and apparatus as depicted in Exhibits A and B, as well as the processes the apparatus depicted in Exhibits A and B performs.

(exhibit 'B' only shows multi-nozzle printers. It is silent on simultaneous deposition and other features)

16. The Hu reference discloses the same teaching as the unpublished manuscript and was published three years prior to the filing date.

17. Hu does not disclose the multi-nozzle printer, as per exhibit 'B'.

18. Sun et al. disclose (pg. 93. col. 2) that multi-nozzle ink jet printers are commonly used (the motivation to combine) in rapid prototyping processes:

> *Three-dimensional printing* (3-DP), creates models by spraying liquid binder through ink-jet printer nozzles on to a layer of metallic or ceramic precursor powder.

This is in the context of pg. 85, col. 1:

> Tissue engineering, the science and engineering of creating functional tissues and organs for transplantation, integrates a variety of scientific disciplines to produce physiologic 'replacement parts' for the development of viable substitutes, which restore, maintain or improve the function of human tissues [1-8]. The principles of tissue engineering is that tissues can be isolated from a patient, expanded in tissue culture and seeded into a scaffold prepared from a specific building material to form a scaffold guided three-dimensional (3-D) tissue [9].

Response to Arguments

19. Applicant's arguments, filed 11/10/2010, have been carefully considered and are not persuasive.

20. The 131 affidavit (11/10/2010) is not persuasive as explained. Applicant's other arguments have been addressed in the rejections applied above.

Conclusion

21. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- Landers et al. (of record; IDS of 10/26/2007) discloses:

Desktop manufacturing of complex objects, prototypes and biomedical scaffolds by means of computer-assisted design combined with computer-guided 3D plotting of polymers and reactive oligomers

*Rüdiger Landers, Rolf Mülhaupt**

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 11/10/2010 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hugh Jones whose telephone number is (571) 272-3781. The examiner can normally be reached on M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kamini Shah can be reached on (571) 272-2279. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Hugh Jones/
Primary Examiner, Art Unit 2128